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- performing a fractionation by partial dissolution of a precipitate of hemoglobin hyperpolymers; or

- performing at least one of the steps above or any combination of them; and

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separating the hyperpolymeric hemoglobin into different fractions based on its molecular weight.

#### REMARKS

The last office action of May 4, 2000 has been carefully considered. Claims 6-9 and 11-15 are in the case.

Claims 6-14 and 16 were rejected as being read on by the cited prior art Poetzsche and Barnikol, Biomater. Art Cells and Immob. Biotechn., 20, 287-91 (1992). Applicant has argued that the method described in Poetzsche described only an analytical method and not a preparative method as is being claimed. The rejection was based on the assertion that the claims did not limit themselves to a preparative method, but also described an analytical method. The claims have been amended to more clearly reflect that the claimed method is a preparative one. Poetzsche does not anticipate a preparative method. The analytical and preparative use of a physiochemical method are not the same. That a method functions on one scale says nothing about the possibility of the ability to scale-up the method. An analytical method merely goes to the ability to detect the distribution of hydrodynamic molecular weights in a sample, but in no way predicts the ability to separate usable samples. In an analytical method, the test sample is small and is lost by the method of detection. In a preparative method, the sample must survive the detection process (preferably with a high

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yield). Thus, that one is able to detect the separation of cross-linked hyperpolymeric hemoglobin by its molecular weight, is no guarantee that one can preserve such fractions separated by molecular weight.

Claims 6-16 were rejected as being unpatentable over Poetzschke in view of U.S. Patent 4,136,093 (Bonhard). The Poetzschke reference has been overcome by the amendments to the claims as discussed above. Additionally, claims 6-16 were rejected on the combination of Poetzschke and Bonhard because "one would expect the non-cross-linked hemoglobin to separate out from the cross-linked hemoglobin as taught in Bonhard" when ammonium sulfate is applied to the sample. While that may be true, the method claimed uses ammonium sulfate to separate cross-linked hemoglobin from cross-linked hemoglobin to obtain a cross-linked hemoglobin with a smaller molecular weight distribution. Such a procedure is not taught by Bonhard.

Claims 10 and 16 were rejected because the claims are alleged to recite a limitation of using a particular electrolyte solvent for chromatographic separation without proper antecedent basis. These claims have been cancelled.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance, and allowance of the application is respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects, in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's amendment and the case passed to issue.

## Officers

Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

The Commissioner is authorized to charge any fees which may be required to our  
Deposit Account No. 50-0955.

Respectfully Submitted,

~~David Toren~~

~~Reg. No. 19,468~~

Dated: September 29, 2000

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I hereby certify that this correspondence is being transmitted, on September 29, 2000, by facsimile to Examiner Anish Gupta of Group Art Unit 1654 at facsimile no. (703) 308-4242.

